

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 in part, 4 in part, 5, 6-8 all in part, 10-13 all in part, drawn to a method for identifying a compound for modulating the interaction of PTPL1 with TAPP.

Group II, claim(s) 1 in part, 2, 3, 4 in part, 6 in part, 10 in part, 11 in part, drawn to a method for identifying a compound that modulates the interaction of TAPP with PtdINs(3, 4) P2.

Group III, claim(s) 1 in part, 4 in part, 6 in part, 10 in part, 11 in part, drawn to a method of modulating the cellular location of TAPP.

Group IV, claim(s) 7 in part, 8 in part, 12 in part, 13 in part, drawn to a method for selecting a compound for modulating the intracellular localization of PTPL1

Group V, claim(s) 9 in part, drawn to a kit comprising TAPP and PTPL1

.Group VI, claim(s) 9 in part, drawn to a kit comprising a polynucleotide encoding TAPP and a polynucleotide encoding PTPL1.

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Group VII, claim(s) 18 in part, and 19 in part, drawn to a method of treating a patient in need of inhibition of apoptosis comprising administration of a compound that inhibits the interaction of PtdIns(3, 4)P2 with TAPP.

Group VIII, claim(s) 18 in part and 19 in part, drawn to a method of treating a patient in need of inhibition of apoptosis comprising administration of a compound that inhibits of TAPP with PTPL1.

Group IX, claim(s) 20 in part and 21 in part, drawn to a method of treating a patient in need of promotion of apoptosis comprising administration of a compound that inhibits the interaction of PtdIns(3, 4)P2 with TAPP.

Group X, claim(s) 20 in part and 21 in part, drawn to a method of treating a patient in need of promotion of apoptosis comprising administration of a compound that inhibits the interaction of TAPP with PTPL1.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: multiple distinct processes and products are claimed (see also MPEP 1850). Pursuant to 37 CFR 1.475, a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention "). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

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- (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and a process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

In the instant case, the first claimed product is Group V, a kit comprising TAPP and PTPL1. There is no method of making said product or utilizing said product recited in the claims of the instant application.

Species Election #1

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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Diseases in a patient in need of inhibition of apoptosis:

- a. diabetes
- b. ischaemic disease
- c. requirement for wound healing
- d. requirement of nerve regeneration

If either of **Groups VII or VIII** are elected, Applicant is required, in reply to this action, to elect a single species (**a-d**) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Claim 18.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disease or pathological condition listed has a different and unique etiology, disease process and outcome and the diseases are not obvious variants of each other as recognized by the art.

Species Election #2

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Diseases in a patient in need of promotion of apoptosis:

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1. cancer
2. inflammation

If either of **Groups IX or X** are elected, Applicant is required, in reply to this action, to elect a single species (**1 or 2**) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Claim 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disease or pathological condition listed has a different and unique etiology, disease process and outcome and the diseases are not obvious variants of each other as recognized by the art.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/ Ph.D.

Primary Examiner, Art Unit 1647

/S. H. S./

Examiner, Art Unit 1647